

REMARKS

Applicant is grateful for the assistance of Examiner Gitomer in constructing amendments to the claims that bring them into conformance with the specification and the statute. Claim 39 has been amended, as agreed, to limit the protein to lipid transferase proteins which are described, for example, on page 2 on page 9 of the specification as the appropriate proteins whose assay may be conducted in the manner claimed.

Importantly, subparagraph (a)(ii) of claim 39 has been modified to clarify the nature of the normalizer in a manner consistent with the specification and the exemplified embodiment. Support for the normalizer being embodied as reagents that develop color such that the light emitted by the fluorophore label coupled to the transferred lipid is absorbed in proportion to the amount of acceptor available is found, for example, on page 7 at the end of the first full paragraph and in the exemplified illustrative embodiment involving CETP set forth on pages 11-12 of the specification in the bridging sentence. It is believed that the proposed amendments to claim 39 are those agreed upon at the interview. As further agreed, claims 40-43 have been canceled – claim 40 as inconsistent with the amendment to claim 39 and claims 41-43 as redundant with the embodiment claimed in claim 44.

Claim 44 has been amended to clarify that CE or TG are surrogates for concentration of the acceptors VLDL and/or LDL in the sample, and claims 47 and 48 have been added to illustrate that reagents which create the normalizing color in an assay for CETP are indeed described in the specification. Support for these claims is found on page 12 of the specification. In addition, what is now subparagraph (a)(ii) has been modified to clarify that the color absorbs the light emitted by the fluorophore. No new matter has been added.

Entry of the amendment, though made after final rejection, is believed proper in light of the agreement that these amendments place the claims in a position for allowance.

Applicant appreciates that the claims have not been rejected over the art.

The Rejection Under 35 U.S.C. § 112, First Paragraph

In view of the amendments kindly suggested by Examiner Gitomer, the following discussion may be moot. However, applicant believes it necessary to respond to the written rejections to complete the record.

The Office takes the position in the written rejection that the application as originally filed does not enable the newly submitted claims. The Office is correct that the assay contains a normalizer component. For illustration, the normalizer component in an assay for CETP is described in detail on page 12. The Office contends that the example on page 12 is insufficiently detailed to follow; however, the required reagents and their amounts are clearly set forth. It is correct that there are no data regarding this assay; however, it is unclear on what basis the Office asserts that such data are necessary. The manner of conducting the assay has been described and no reason has been provided to doubt that the assay works as set forth in the specification.

It is correct that the only illustration of specific reagents is set forth with regard to an assay for CETP; however, once the concept of creating a normalizing color has been described, it is well within the skill of the art to provide analogous normalizing reactions with respect to acceptor proteins for moieties which are transferred by other transferases, such as those listed on page 2 of the specification, microsomal triglyceride transfer protein (MTP), phospholipid transfer protein (PLTP) and lecithin cholesterol acyl transferase (LCAT).

Applicant further agrees that the specification defines a problem to be solved, but disagrees that the solution is not provided. The solution is to create a color in proportion to the concentration of acceptor that absorbs fluorescence emitted when the labeled substance is transferred. It is also correct that novelty resides in the use of a normalizer as in claim 39(a)(ii) or claim 44(a)(i) (sic, 44(a)(ii)). As noted, the normalizer does not need to be a single substance, but rather can be a substance generated by a multiplicity of reagents.

Thus, the specification illustrates the manner of conducting the assay specifically in the case of CETP, and it is within the skill of the art to design alternate formats for comparable transferases. It is believed that the amendments to the claims clarify the nature of the normalizer and limit the invention to the illustrated embodiment as well as alternatives that are quite similar and for which extrapolation from the illustrated embodiment is within ordinary skill.

The Rejection of Claims 39-46 Under 35 U.S.C. § 112, Second Paragraph

It is asserted that the claims are indefinite because various aspects of the assay are described in functional terms where one would not know what compounds are intended. The amendments to the claims directly address this criticism. Claim 39 has been limited to lipid transferases and the label attached to the lipid has been limited to a fluorophore. The normalizer has been articulated as reagents which generate a color in proportion to the acceptor. In light of the amendments to the claims, it is respectfully submitted that the rejection for indefiniteness may be withdrawn.

Conclusion

It is believed that the specification, by providing a detailed illustration for determination of CETP and by indicating the functionality and nature of the components of the assay adequately

describes the invention as now claimed. Applicant is appreciative of the assistance of Examiner Gitomer in constructing amendments in conformance with the specification. Therefore, applicant respectfully requests that the pending claims, claims 39 and 44-48, be passed to issue.

If details remain that might be resolved by telephone, such a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 527832000300.

Respectfully submitted,

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